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GMP Certification Programme
Certified Biotech Manager

Speakers



Dr Rüdiger Alt
Novartis



Dr Rainer Gnibl
Local Government of Upper Bavaria



Dr Sabine Hauck
Chair of ECA ATMP Interest Group



Dr Ulrich Kissel
Chair of ECA ATMP Interest Group

GMP for ATMPs

Made simple

14/15 October 2025 | Heidelberg, Germany



Highlights

- Definitions and Key Regulations of ATMP and GMP
- Risk-based Approach
- Environmental Monitoring and (Cross) Contamination
- Raw/Starting Materials
- Handling of Quality Defects

Basic Training for Beginners & Newcomers

Objective

In this basic GMP course for ATMPs (Advanced Therapy Medicinal Products), experts from authorities, industry and consultancy will explain the basic GMP requirements for working with ATMPs. In addition, you will gain an understanding of the most important regulatory requirements in this area.

Background

Advanced therapy medicinal products (ATMPs) play a key role in innovative, personalized medicine. They are leading biomedical research and providing breakthrough treatments for serious and often incurable diseases. These therapies include CAR-T cells, viral vectors (AAV, lentiviruses, adenoviruses), plasmid DNA and tissue engineering, all driven by advances in genetics, molecular biology and cell biology.

GMP compliance is essential for the consistent, traceable manufacture and control of medicines. To achieve this, employees must understand the basic rules. In practice, this understanding is often incomplete. This training gives you an insight in the GMP rules for ATMPs starting from the basics.

Target Audience

This basic course is aimed at Quality Assurance, Quality Control and Production personnel who work with ATMPs on a daily basis. This course will refresh or create a basic understanding of GMP with a focus on ATMPs.

This course provides new employees and employees in their first years of employment with an initial insight into GMP regulations, as well as the day-to-day characteristics and GMP-compliant handling when working with ATMPs.

Moderator

Clemens Mundo, Concept Heidelberg



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Programme

GMP – A first Approach

Dr Sabine Hauck

- Definition, context and history
- What makes GMP so special?
- GMP outside Europe

ATMPs – Modern Medicines between Cells and Genes

Dr Sabine Hauck

- To be or not to be - which products belong to ATMPs?
- A decision tree to help you
- Regulation 1394/2007

Risk-based Approach

Dr Sabine Hauck

- Flexibility and responsibility
- Understanding of processes and products as a prerequisite
- Application and examples

Outsourced Activities

Dr Ulrich Kissel

- Scope and importance
- Supplier management
- Specification management
- Change control

Personnel & Rooms

Dr Rainer Gnibl

- Requirements for ATMP personnel
- „Shared“ or “dedicated” facilities?
- EU-GMP compliant design

Equipment - Single Use and more

Dr Ulrich Kissel

- Scope and importance
- Sterility management
- Handling SUS in storage and operation
- Special features, Teflon

Aseptic Environment, Environmental Monitoring and (Cross-)Contamination

Dr Rainer Gnibl

- Principles of particulate and microbiological monitoring
- Avoidance of (cross) contamination
- Basics of aseptic production

Handling of Raw/Starting Materials, Cell Bank System and more

Dr Rainer Gnihl

- Requirements for various materials
- Incoming goods
- Traceability

Quality Control

Dr Ulrich Kissel

- Scope and importance
- Pharmacopoeia Europaea
- Samples and their handling
- Method validation and method transfer

Qualification & Validation

Dr Rainer Gnihl

- Cleanroom qualification
- Basics of process and cleaning validation
- Aseptic validation (media fill)
- Validation life cycle

Batch Release

Dr Rüdiger Alt

- Batch certification and release by the EU QP
- Batch certification before fully completed testing
- Decentralized production

Handling of unplanned Deviations

Dr Rüdiger Alt

- Recording and documentation
- Initial evaluation and classification
- Root Cause Investigation & CAPA

Handling of OOS Results

Dr Rüdiger Alt

- OOS investigation and risk assessment
- Exceptional provision request
- Exceptional batch supply and notification to authorities

Often forgotten GMP Areas

Dr Ulrich Kissel

- Reconstitution after batch release
- Data with regards to ATMPs and GMP Annex 11
- Temperature management - Is it really necessary?
- Purchasing and Supply Chain Management and GMP

Specific Guidelines for selected Product Types

Dr Sabine Hauck

- Supplementary requirements for manufacture and control
- Requirements for product properties and characterization
- Examples for product-related guidelines

Speakers



Dr Rüdiger Alt
Novartis

Qualified Person for AT(I)MPs

Dr Rüdiger Alt joined Cytonet in 2013 as Deputy Head of QC/QA and QP. Since 2015, he has been responsible for cell- and vector-based AT(I)MPs as QP at Novartis.



Dr Rainer Gnihl

Local Government of Upper Bavaria
GMP Inspector for EMA and local Government

Dr Rainer Gnihl is pharmacist and GMP Inspector for the District Government of Upper Bavaria and the EMA and performs GMP-inspections worldwide. Before that, he was working for the Bavarian Ministry of Environment and Health. Rainer Gnihl also holds a lectureship at the University Erlangen-Nürnberg.



Dr Sabine Hauck

dequra pharma consult hauck

Sabine Hauck has 20+ years of experience in the biotech industry, in which she held various positions in pharmaceutical development, quality assurance, regulatory affairs and corporate development. Her product experience spans from small molecules to cell therapies and includes a variety of dosage forms. After gaining experience in several biotech companies she is now providing freelance consulting and trainings for biotech and biopharma companies in the field of pharmaceutical development, quality assurance, and regulatory affairs. Sabine is also active as the chair of the ECA ATMP interest group.



Dr Ulrich Kissel

KisselPharmaConsulting GmbH

Ulrich Kissel is Qualified Person and Chairman of the Board of Directors of the European Qualified Person Association (EQPA). He works as a GMP consultant and contract QP to the Pharmaceutical Industry. Previous to his current role he held leadership positions in Quality and Supply Chain and served for many years as QP for Roche.

Social Event

On Tuesday evening, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.



If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

GMP for ATMPs
14/15 October 2025, Heidelberg, Germany

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

City

ZIP Code

Country

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P.O. Box 101764
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D-69007 Heidelberg
GERMANY

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Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date

Tuesday, 14 October 2025, 09.00 h – 17.00 h
(Registration and Coffee 8.30. h – 09.00 h)
Wednesday, 15 October 2025, 08.30 h – 17.00 h
All times mentioned are CEST

Venue

Intercity Hotel Heidelberg
Kurfürsten-Anlage 81
69115 Heidelberg, Germany
Phone: +49/6221/1881 0
Email: heidelberg@intercityhotel.com

Fees (per delegate, plus VAT)

ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The conference fee is payable in advance after receipt of invoice and includes dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Registration

Via the attached reservation form, by e-mail or by fax – **or search and register directly at www.gmp-compliance.org under the number 21967.**

Presentations/Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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